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ROYDS, LESLIE A	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,141	YAACOBI, YOSEPH	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/30/04;4/26/04;2/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 are presented for examination.

Acknowledgment is made of the instant application as a divisional of U.S. Patent Application No. 10/187,006, filed July 1, 2002, now U.S. Patent No. 6,669,950, which is a continuation of U.S. Patent Application No. 09/664,790, filed September 19, 2000, now U.S. Patent No. 6,416,777, which claims benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/160,673, filed October 21, 1999.

Applicant's Information Disclosure Statements (IDS) filed January 20, 2004 (four pages), April 26, 2004 (one page) and February 3, 2005 (one page) have each been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08(a-b) (six pages total), the Examiner has considered the cited references.

Applicant's response filed August 14, 2007 to the requirement for restriction/election dated April 6, 2007 has been received and entered into the present application. Pursuant to the notice dated October 24, 2007, Applicant's reply of August 14, 2007 was non-compliant. Applicant's subsequent response filed November 6, 2007 in reply to the notice of non-responsive amendment has been received and entered into the present application.

Requirement for Election of Species

Applicant's election of drugs for the treatment of age-related macular degeneration in the reply filed August 14, 2007, and the election of the specific species of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as the pharmaceutically active agent for ocular delivery is acknowledged by the Examiner. Because Applicant did not distinctly and specifically point out the supposed errors in the requirement, the election has been treated as an election **without traverse** (MPEP §818.03(a)).

Therefore, for the reasons above and those made of record at pages 2-5 of the previous Office Action dated April 6, 2007, the requirement remains proper and is hereby made **FINAL**.

The claims corresponding to the elected subject matter are claims 1-5 and such claims are herein acted on the merits.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Present claim 2 is directed to the method of delivering a pharmaceutically active agent to the eye as defined in claim 1, wherein said disposing step comprises disposing said tablet proximate said macula. Present claim 3 further defines the disposing step as disposing said tablet generally above said macula.

The term "proximate" in claim 2 and the phrase "generally above" are relative terms that render the claim indefinite. The term "proximate" or the phrase "generally above" is not defined by the claims or the specification as to the degree(s) of proximity is tolerated by the claim such that the skilled artisan would have been reasonably apprised of the metes and bounds of the location(s) in which the tablet may be disposed relative to the macula. For example, should the tablet be placed directly above the macula to meet the claim(s)? Or would placement at 135° relative to the placement of the macula still meet the claim? In view of these facts, the skilled artisan would not have been reasonably apprised of the subject matter for which Applicant is presently seeking protection.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Interpretation of the Term "Tablet" for Examination

Applicant's instant claim 1 is directed to a method of delivering a pharmaceutically active agent to the eye, said eye having a sclera, a Tenon's capsule, a macula, and an orbit, comprising the steps of providing a tablet having a concave, dome-shaped scleral surface and pharmaceutically active agent disposed therein, and disposing said tablet on an outer surface of said sclera and below said Tenon's capsule.

Though Applicant fails to provide a formal definition of the term "tablet" in the present disclosure, the specification describes the tablet in the paragraph bridging pages 9-10, which states:

"An inner core **81**, which is shown in FIG.10, is preferably disposed in well **20**. As shown in FIG.10, inner core **81** is preferably a tablet comprising one or more pharmaceutically active agents. Tablet **81** preferably has a generally oval body **46** with a concave, dome-shaped, scleral surface **85** and a convex, dome-shaped, orbital surface **86**. Body **46** also preferably has a peripheral bevel **87** disposed thereon. Alternatively, as shown in FIG.11, the inner core may comprise mating, half-oval tablets **82a** and **82b**. Tablet **82a** preferably has a body **48** equal to the opposite half of body **46** of tablet **81**. Still further in the alternative, inner core **81**, or inner cores **82a** and **82b**, may comprise a conventional hydrogel, gel, paste, or other semi-solid dosage form having one or more pharmaceutically active agents disposed therein." (p.9, l.23-p.10, l.8)

Such disclosure supports the interpretation of the term "tablet" as circumscribing a solid (or, alternatively, also a semi-solid) dosage form in which a pharmaceutically active agent is contained therein for application to the eye as described. This interpretation is consistent with the broadest, most reasonable interpretation consistent with the art as described in MPEP §2111, as evidenced by Stedman's Medical Dictionary (Twenty-Second Edition, 1972; p.1250), which defines a tablet as "a solid dosage form containing medicinal substances with or without suitable diluents; may vary in shape, size, and

weight; may be classed according to the method of manufacture, as molded tablets and compressed tablets."

For these reasons, examination of the instant claims will proceed using the interpretation of the term "tablet" as a solid (or semi-solid) dosage form containing a medicinal substance (in this case, a pharmaceutically active agent, of which Applicant has specifically elected the agent 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate for examination on the merits).

Claim Rejections - 35 USC § 103

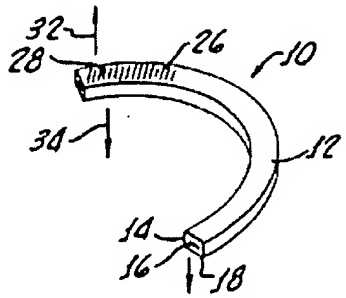
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gwon et al. (U.S. Patent No. 5,476,511; 1995) in view of Clark (U.S. Patent No. 5,679,666; 1997), citing to eMedicineHealth (http://www.emedicinehealth.com/anatomy_of_the_eye/article_em.htm; 2007) and Biology-Online (http://www.biology-online.org/dictionary/Tenons_capsule; 2005), each to show facts.

Gwon et al. teaches a system providing controlled release of an active agent in an eye that has a means defining a shape thereof for enabling placement of the device under a conjunctiva of an eye, wherein the arcuate shape is specifically designed for preventing migration of the device in the eye after placement under the conjunctiva (col.1, l.66-col.2, l.6 and col.3, l.61-63) and the device is formed from a material permeable to the passage of active agent, such as polymeric materials (col.3, l.25-28), and an active agent is provided and disposed in the device (col.2, l.11-13). Suitable drugs can be used with the disclosed ocular implant for therapy of the eye, such as neovascular inhibitors for macular degeneration (col.4, l.62-64), and the device may also include a means to enable diffusion of the active agent out of the

implant at a selected rate (col.2, l.47-50). Gwon et al. discloses a method for disposing the disclosed device (identified as **10**, see the device depicted in Figure 1 reproduced below), wherein the device is disposed in the subconjunctival area of the eye (identified as **40**, see Figure 3) by injecting a short-acting anesthetic, such as xylocaine, under the conjunctiva, incising the conjunctiva/Tenon's (understood to refer to Tenon's capsule) to reveal the scleral surface and threading the device (**10**) through the incision to rest flat on the sclera (note that this step meets Applicant's claimed limitation directed to the disposition of the "tablet" on the outer surface of the sclera but below Tenon's capsule; col.6, l.65-col.7, l.14). Advantages of the disclosed device are the elimination of the need to self-administer ophthalmic preparations (col.2, l.14-19). Gwon et al. depicts the following device as representative of the disclosed invention:



(Figure 1).

Note that the arcuate shape of the device and its placement on the scleral surface so that it lays flat clearly meets Applicant's claimed limitations directed to the "tablet" (i.e., the delivery device, see *supra*) having a concave, dome-shaped scleral surface (i.e., the inner surface to be placed flat against the sclera) and a convex, dome-shaped orbital surface (i.e., the outer surface facing the orbit). Note also that, absent any specific definition of what is meant by "proximate" or "generally above" said macula, the teachings of Gwon et al. clearly meet both requirements because, as evidenced by the placement of the device as shown in Figure 3, the device is within the vicinity of (i.e., proximate) to the macula and is "generally above" the macula by virtue of its position on the outer eyeball surface adjacent to the cornea.

Though Gwon et al. does not expressly teach that the eye to be treated has a sclera, Tenon's capsule, macula and orbit *per se*, eMedicineHealth is cited for its factual teachings that the human eye

(such as that referenced in Gwon et al.) necessarily contains a sclera (the white part of the eye), macula (the central portion of the retina) and orbit (the eye socket). Please see p.1-4. Biology-Online is cited for its factual teaching that the human eye (such as that referenced in Gwon et al.) also necessarily contains a Tenon's capsule, which is the fascial sheath of the eyeball contained on the outer surface of the sclera (p.1).

Regarding the application of eMedicineHealth and Biology-Online as factual evidence, Applicant is directed to MPEP §2124, which teaches that in certain circumstances, a factual reference need not antedate the filing date of the instant application. Specifically, "In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 D.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism." Accordingly, both eMedicineHealth and Biology-Online are properly relied upon, despite the fact that they were published in 2007 and 2005, respectively, because each teaches a well-known scientific fact, i.e., the anatomical structures of the human eye.

Gwon et al. fails to teach the specific use of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as the pharmaceutically active agent for use in the ophthalmic drug delivery device.

Clark is cited for its teachings of angiostatic agents useful for the inhibition of neovascularization of the eye, such as that which occurs in the front of the eye (i.e., the cornea, iris and trabecular meshwork), as well as the back of the eye (i.e., retinal, subretinal, macular, and optical nerve head; col.2, l.4-21), wherein a preferred angiostatic agent is the compound 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as a preferable angiostatic agent (col.3, l.42-46). Clark further discloses the preferable use of topical formulations of the disclosed angiostatic agents, such as in the form of an aqueous solution, suspension, ointment, or gel, as long as the formulation is capable of penetrating the eye tissue (col.4, l.66-col.5, l.6), and further wherein the topical formulation may be administered to the surface of the eye one to six times daily (col.5, l.10-12).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to include 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate into the ophthalmic delivery device of Gwon et al. because Gwon et al. teaches a means for topically delivering ophthalmic drugs directly to the eye while eliminating the need for self-administration and Clark teaches an ophthalmic preparation of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as a potent angiostatic agent to reduce ocular neovascularization. Such a person would have been motivated to do so by a desire to provide an effective means of administration of the ophthalmic 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate solution to an eye in need of treatment or inhibition of ocular neovascularization, such as that associated with macular degeneration, which, in turn, would have facilitated use (and compliance with a prescribed regimen) of the drug by a patient in need of its therapeutic effects. Furthermore, it is noted that the delivery device of Gwon et al. would have been necessarily capable of delivering any known ophthalmic preparation to the eye, particularly 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, due to the physical structure of the device, which imparts the ability to dispense a pharmaceutically active agent directly to the eye tissue over a period of time while eliminating the need for frequent self-administration of a topical ophthalmic formulation, as well as its amenability for use proximate to (or directly into) the eye surface, absent factual evidence to the contrary.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the

scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-25 and 28-30 of U.S. Patent Application No. 11/248,727 in view of Clark (U.S. Patent No. 5,679,666; 1997).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending application are not considered patentably distinct from each other because the pending claims are obvious over the copending claims.

The copending claims clearly provide for a method of delivering a pharmaceutically active agent to an eye that comprises a sclera, macula, Tenon's capsule, and superior and lateral rectus muscles, comprising the step of providing a drug delivery device of arc-shaped geometry that facilitates implantation of the device on the outer surface of the sclera and below Tenon's capsule, wherein the active agent is disposed proximate to the macula, such as above the macula. The copending claims further provide for the body of the device to have a scleral and orbital surface on the arc (i.e., meets the instantly claimed requirement for a concave, dome-shaped scleral surface and a convex, dome-shaped orbital surface; see instant claims 1 and 5) comprising a tablet containing a pharmaceutically active agent.

Though the copending claims provide for the inclusion of a pharmaceutically active agent in the inner core (i.e., tablet) of the device, but fail to specifically recite the use of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, Clark is cited for its teaching of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as an effective angiostatic agent to inhibit ocular neovascularization (col.2, l.4-21 and col.3, l.42-46). One of ordinary skill in the art at the time of the invention would have found it *prima facie*

obvious to include an agent, such as, e.g., 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, into the drug delivery device of the copending claims. Such a person would have been motivated to do so by a desire to provide an effective means of administration of the ophthalmic preparation to an eye in need of treatment or inhibition of neovascularization, which, in turn, would have facilitated use, and compliance with a prescribed regimen, of the drug by a patient in need of its therapeutic effects. Furthermore, it is noted that the copending delivery device would have been fully capable of delivering any known ophthalmic preparation to the eye, including 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, due to its physical structure and amenability for use proximate to (or directly on) the eye surface, absent factual evidence to the contrary.

Moreover, the skilled artisan would have also found it *prima facie* obvious to formulate the drug delivery device to provide diffusion and release of the pharmaceutically active agent in a controlled manner over a period of time so as to maintain consistently therapeutically effective levels of the active agent within the eye.

Accordingly, provisional rejection of claims 1-5 is proper over claims 23-25 and 28-30 of U.S. Patent Application No. 11/248,727 as claiming obvious and unpatentable variants thereof.

Claims 1-5 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 5-6, 8-11, 13 and 15-16 of U.S. Patent No. 6,413,540 in view of Biology-Online (http://www.biology-online.org/dictionary/Tenons_capsule; 2005).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and

those of the copending applications are not considered patentably distinct from each other because the pending claims are obvious over the patented claims.

The patented claims clearly provide for a method of delivering a pharmaceutically active agent, such as 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, to an eye by providing a drug delivery device that has an inner core comprised of a tablet or hydrogel that comprises the active agent on the scleral surface of the device, wherein the scleral surface has a geometry that mates with the sclera (implies a concave-convex design to mate with the spherical nature of the eyeball) and further wherein the device is placed within the eye such that the active agent is in communication with the sclera. The patented claims further provide for the disposition of the device generally above the macula.

Though this embodiment of the patented claims does not specify that the device is placed below Tenon's capsule as presently claimed, the patented claims specify placement of the device onto the scleral surface, which requires it to be below Tenon's capsule because, as evidenced by Biology-Online, Tenon's capsule is found on the outer surface of the sclera. Please see p.1. Note that Biology-Online was published in 2005, but is properly relied upon because it teaches a well-known scientific fact, i.e., the anatomical structures of the human eye, and, thus, need not antedate the filing date of the instant application in accordance with MPEP §2124.

Moreover, the skilled artisan would have also found it *prima facie* obvious to formulate the drug delivery device to provide diffusion and release of the pharmaceutically active agent in a controlled manner over a period of time so as to maintain consistently therapeutically effective levels of the active agent within the eye.

Accordingly, rejection of claims 1-5 is proper over claims 3, 5-6, 8-11, 13 and 15-16 of U.S. Patent No. 6,413,540 as claiming obvious and unpatentable variants thereof.

Claims 1-5 are rejected on the grounds of nonstatutory obviousness-type double patenting as

being unpatentable over claims 20-24, 26-27 and 31 of U.S. Patent No. 6,416,777.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are obvious over the patented claims.

The patented claims clearly provide for a method of delivering a pharmaceutically active agent, such as 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, to an eye by providing a drug delivery device that has an inner core comprised of a tablet or a semi-solid form that comprises the active agent on the scleral surface of the device, wherein the scleral surface has a radius of curvature substantially equal to the radius of curvature of the eye (implies a concave-convex designed to mate with the spherical nature of the eyeball, as further evidenced by patented claim 31 directed to the C-shaped geometry of the device) and further wherein the device is placed on the outer surface of the sclera within the eye beneath Tenon's capsule. The patented claims further provide for the disposition of the device above the macula.

Moreover, the skilled artisan would have also found it *prima facie* obvious to formulate the drug delivery device to provide diffusion and release of the pharmaceutically active agent in a controlled manner over a period of time so as to maintain consistently therapeutically effective levels of the active agent within the eye.

Accordingly, rejection of claims 1-5 is proper over claims 20-24, 26-27 and 31 of U.S. Patent No. 6,416,777 as claiming obvious and unpatentable variants thereof.

Claims 1-5 are rejected on the grounds of nonstatutory obviousness-type double patenting as

being unpatentable over claims 23-27 of U.S. Patent No. 6,808,719 in view of Clark (U.S. Patent No. 5,679,666; 1997).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the claims of the instant patent application and those of the copending applications are not considered patentably distinct from each other because the pending claims are obvious over the patented claims.

The patented claims clearly provide for a method of delivering a pharmaceutically active agent to the eye comprising the steps of providing a drug delivery device comprising a body having a pharmaceutically active agent disposed therein and disposing the device on the outer surface of the sclera but below Tenon's capsule, wherein the device is a tablet that contains the active agent and the tablet is disposed proximate to, preferably generally above, the macula of the eye, and further wherein the tablet is formulated to bioerode and release the active agent at a controlled rate.

Though the patented claims provide for the inclusion of a pharmaceutically active agent in the device, but fail to specifically recite the use of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, Clark is cited for its teaching of 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate as an effective angiostatic agent to inhibit ocular neovascularization (col.2, l.4-21 and col.3, l.42-46). One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to include an agent, such as, e.g., 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, into the drug delivery device of the patented claims. Such a person would have been motivated to do so by a desire to provide an effective means of administration of the ophthalmic preparation to an eye in need of treatment or inhibition of neovascularization, which, in turn, would have facilitated use, and compliance with a prescribed regimen,

of the drug by a patient in need of its therapeutic effects. Furthermore, it is noted that the patented delivery device would have been fully capable of delivering any known ophthalmic preparation to the eye, including 4,9(11)-Pregnadien-17α,21-diol-3,20-dione-21-acetate, due to its physical structure and amenability for use proximate to (or directly on) the eye surface, absent factual evidence to the contrary.

Though the patented claims do not specify the exact geometrical shape of the device as instantly claimed, i.e., that it has a concave, dome-shaped scleral surface and a convex dome-shaped orbital surface, one of skill in the art at the time of the invention would have found it *prima facie* obvious to shape the device to be implanted into such a design to facilitate implantation and adherence to the spherical eyeball surface, as well as to enhance the patient's comfort by providing a non-obtrusive implant that shapes to the natural curvature of the eye.

Accordingly, rejection of claims 1-5 is proper over claims 23-27 of U.S. Patent No. 6,808,719 as claiming obvious and unpatentable variants thereof.

Conclusion

Rejection of claims 1-5 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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